

BIONAFEM- levonorgestrel tablet
Bionpharma Inc.

The sooner you take it, the more effective it will be. Take as soon as possible within 72 hours.

Drug Facts

Active ingredient

Levonorgestrel, USP 1.5mg

Purpose

Emergency contraceptive

Use

for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings

Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel

Sexually transmitted diseases (STDs) alert: This product does **not** protect against HIV/AIDS or other STDs.

Do not use

- if you are already pregnant (because it will not work)
- for regular birth control

Ask a doctor or pharmacist before use if you are

taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These medications may reduce the effectiveness of levonorgestrel.

When using this product you may have

- menstrual changes
- nausea
- lower stomach (abdominal) pain
- tiredness
- headache
- dizziness
- breast pain
- vomiting

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- **take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it, the better it will work.**
- **if you vomit within 2 hours after taking the medication, call a healthcare professional to find out if you should repeat the dose**

Other information

- **read the instructions, warnings, and enclosed product leaflet before use**
- this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation).
- **do not use if carton is open or tear strip is removed or blister seal is broken or missing**
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate, potato starch, talc

Questions or comments?

For more information, call toll free **1-888-235-2466** weekdays

†Plan B One-Step® is a registered trademark of Women's Capital Corporation

Distributed by:

BIONPHARMA

600 Alexander Road,

Princeton, NJ 08540

Manufactured by:

Glenmark Pharmaceuticals Ltd.

Colvale-Bardez, Goa 403513, India

MADE IN INDIA

GO/DRUGS/785

01/19

Package Label.Principal Display Panel

NDC 69452-243-60

†**Compare to** the active ingredient of **Plan B One-Step®**

BionaFem™

Levonorgestrel Tablet 1.5 mg

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-243	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)		LEVONORGESTREL	1.5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYDROXYMETHYLCELLULOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
STARCH, POTATO (UNII: 8I089SAH3T)				
TALC (UNII: 7SEV7J4RIU)				
Product Characteristics				
Color	WHITE (off-white)	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	G;78	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-243-60	1 in 1 CARTON	04/14/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA207044		04/14/2019	

Labeler - Bionpharma Inc. (079637826)

Registrant - Glenmark Pharmaceuticals Limited (650425929)

Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		677318665	MANUFACTURE(69452-243)

